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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,925	02/26/2002	John Edward More	697.004US2	4853

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EXAMINER	
MOHAMED; ABDEL A	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/082,925	MORE ET AL.	
	Examiner	Art Unit	
	Abdel A. Mohamed	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-30,32 and 34-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *27-30 and 34-37* is/are allowed.

6)☒ Claim(s) *32, 38-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

ACKNOWLEDGMENT OF AMENDMENT, REMARKS AND STATUS OF THE CLAIMS

1. The amendment and remarks filed 7/22/04 are acknowledged, entered and considered. In view of Applicant's request claims 27-30, 32 and 34 have been amended, claims 35-45 have been added and claims 31 and 33 have been canceled. Claims 27-30, 32 and 34-45 are now pending in the application. The objections to the abstract and trademarks and the rejections under 35 U.S.C. 101, 35 U.S.C. 112, second paragraph and 35 U.S.C. 102(b) over the prior art of record are withdrawn in view of Applicant's amendment and remarks filed 7/22/04.

The followings are new ground of rejections necessitated by Applicant's amendments:

CLAIMS REJECTION-35 U.S.C. 112, 1st PARAGRAPH

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32 and 39-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject

matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no description in the instant specification for the claimed **method of treating drug toxicity let alone that caused by drug overdose in a patient**, wherein the drug comprises a tricyclic anti-depressant or a basic drug, wherein the tricyclic anti-depressant is amitriptyline, desipramine, or nortiptyline and the basic drug is quinine, lignocaine or propranol by administering enterally, parenterally, by transmucosal delivery, by an implant, intravenously, intramuscularly or subcutaneously to the patient an effective amount of about 10 g to about 30 g alpha-1-acid glycoprotein (AAG), wherein the AAG comprises less than or equal to 0.1 Eu lipopolysaccharide per mg AAG as claimed in claims 32 and 39-45. The specification on Examples 1-5 demonstrates the purification or removal of LPS from an AAG containing preparation as well as depyrogenating an AAG-enriched fraction with contact by means of ion-exchange chromatography (both anion and cation) in combination with dialysis and/or ultrafiltration. Examples 6 and 7 demonstrate the effect of Aerosil treatment upon endotoxin level; Examples 8-14 show the optimization of Aerosil treatment concentration; Examples 15-17 show the depyrogenation of a final product (i.e., clearance of endotoxin) by Aerosil treatment at high and low concentration; Examples 18-22 demonstrate the optimization of treatment time and Examples 23-25 demonstrate optimization of treatment temperature; Example 26 discloses the effect of prolonged heat on AAG structure while Example 27 discloses the effect of stabilizers on pasteurization of AAG; and Examples 28-31 evaluate other

methods for depyrogenation of AAG. However, there is no method of treating drug toxicity in general or those caused by various over dose drugs by administering in all kinds of mode of administration to the patient an effective amount of AAG, wherein the AAG comprises less than or equal to 0.1 Eu lipopolysaccharide per mg AAG in the manner claimed in claims 32 and 39-45.

CLAIMS REJECTION-35 U.S.C. § 112 2nd PARAGRAPH

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claim 38 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38 is substantially duplicates of claim 34 because claim 34 is directed to a pharmaceutical composition comprising the AAG of claim 27 (note independent claim 27 is directed to an isolated and purified AAG having a LPS concentration of less than or equal to 0.1 Eu/mg AAG) and a pharmaceutically acceptable carrier, excipient, diluent, or combination thereof. Similarly, independent claim 38 is directed to a pharmaceutical composition comprising an isolated and purified depyrogenated AAG comprising less than or equal to 0.1 LPS Eu/mg AAG and a pharmaceutically acceptable carrier, excipient, diluent, or combination thereof. Although, the preamble of claim 38 recites "depyrogenated", but claim 34 depends on claim 27 and incorporates the limitations of claim 27 which has the same concentration of LPS as claim 38 (i.e.,

both have a LPS concentration of less than or equal to 0.1 Eu/mg AAG). Thus, without reciting the term "depyrogenated" one of ordinary skill in the art would understand that in claim 34 the pharmaceutical composition comprising AAG is depyrogenated. As such, there would appear to be no difference in scope between claim 34 (which depends on claim 27) and 38. Hence, both sets of claims appear to claim the same subject matter (See e.g., MPEP 706.03[k]).

OBJECTION OF CLAIMS

4. Claims 41 and 42 are objected in the recitation "anti-depressant" and "antidepressant", respectively because the terms are inconsistent. It is believed to be typographical error. Appropriate correction is required.

ACTION IS FINAL, NECESSITATED BY AMENDMENT

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

CONCLUSION AND FUTURE CORRESPONDENCE

6. Claims 27-30 and 34-37 are allowed and claims 32 and 38-45 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272 0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (571) 272 0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AAM Mohamed/AAM

October 1, 2004

JON WEBER
SUPERVISORY PATENT EXAMINER